

REMARKS

Claims 20-39 are currently pending in the application. Applicants acknowledge that claims 35-39 have been withdrawn from consideration by the Examiner for as being directed to a non-elected invention. By this amendment, claims 20, 21, 26-28, 30-32, and 35 are amended for the Examiner's consideration. The above amendments do not add new matter to the application and are fully supported by the original disclosure. For example, support for the amendments is provided in the claims as originally filed, at Figure 2, and at pages 4-6 of the specification as originally filed. Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

Objection to Claims

Claim 20 is objected to for a grammatical informality. By this response, claim 20 has been amended in accordance with the Examiner's helpful suggestion. Accordingly, Applicants respectfully request that the objection of claim 20 be withdrawn.

35 U.S.C. §112 Rejection

Claims 21, 26, 30, and 31 are rejected under 35 U.S.C. §112, 2nd paragraph. These rejections are respectfully traversed.

Claims 21 and 30 are rejected under §112, 2nd paragraph, as allegedly being narrative in form and replete with indefinite and functional or operational language. While Applicants do not acquiesce in the assertion of indefiniteness of claims 21 and 30, Applicants have, nevertheless, amended claims 21 and 30 to more clearly define the claimed invention. These amendments have been made to clarify previously recited terminology, without narrowing the scope of the claims.

Moreover, Applicants note that functional or operational language does not, in and of itself, render a claim indefinite. To the contrary, MPEP §§ 2173.01 and 2173.05(g) provide the following guidance regarding functional language:

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

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A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

In view of the above-noted passages of the MPEP, Applicants submit that functional recitations in claims 21 and 30, and any other claims, do not render the claims indefinite.

Claim 26 is rejected for using the phrase “such as.” Applicants have amended claim 26 to delete the phrase “such as.”

Claims 30 and 31 are rejected for reciting features that lack antecedent basis in the claims. Applicants do not agree that the lack of antecedent basis renders the claims indefinite, noting that, according to MPEP 2173.05(e), the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Energizer Holdings Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006). Nevertheless, claims

30 and 31 have been amended to more clearly define the claimed invention without affecting the original scope of the claims.

Accordingly, Applicants respectfully request that the §112, 2nd Paragraph, rejection of claims 21, 26, 30, and 31 be withdrawn.

35 U.S.C. §103 Rejection

Claims 20-34 are rejected under 35 U.S.C. §103(a) for being unpatentable over U.S. Patent No. 5,738,824 ("Pfeifer") in view of U.S. Patent No. 5,494,530 ("Graf"). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art. *See, In re Royka*, 490 F.2d 981, 985, 180 USPQ 580, 583 (CCPA 1974); *see also, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). If the prior art reference(s) do not teach or suggest all of the claim limitations, Office personnel must explain why the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art (MPEP 2141).¹ Applicants submit that no proper combination of the applied art teaches or suggests each and every feature of the claimed invention.

The present invention relates to a method and device for measuring and controlling the circulation of fluids in endoscope channels. More specifically, independent claim 20 has been amended to recite:

20. A process for measuring and controlling the circulation of fluids in endoscope channels comprising:
placing at least one endoscope into a tank;

¹ While the *KSR* court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the [Supreme] Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007) (quoting *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007)).

coupling one or more inlet channels of the endoscope to a hermetic chamber having a known volume and one or more valves, the hermetic chamber being equipped with a low level sensor and a high level sensor, and an upper portion of the hermetic chamber being connected to a connection solenoid valve that allows air to evacuate when the hermetic chamber is being filled;

filling the hermetic chamber and valves to a high level position, thereby saturating the tank and inlet channels with a fluid from at least one fluid supply, wherein the filling is performed by a circulation pump arranged upstream of the hermetic chamber and which is configured to agitate contents of the tank;

pressurizing the hermetic chamber using a filtered air compressor;

controlling and recording a time for a fluid flow under pressure within the hermetic chamber to travel from the high level position to a designated low level position when at least one of the valves is open to at least a respective one of the one or more inlet channels; and

confirming that the fluids are circulating in each portion of each channel of the endoscope, that the at least respective one of the one or more inlet channels are properly coupled to the at least one of the valves, and that none of the respective one or more channels are closed.

The Examiner asserts that Pfeifer discloses a tank at element 40, a chamber at element 47, and valves at elements 57. The Examiner acknowledges that Pfeifer does not disclose a hermetic chamber. However, the Examiner asserts that Graf discloses a hermetic chamber, and that it would have been obvious to modify Pfeifer to use a hermetic chamber. Notwithstanding these assertions, Applicants submit that no proper combination of Pfeifer and Graf teaches the combination of features recited in claim 20 as amended.

More specifically, neither Pfeifer nor Graf discloses or suggests *the hermetic chamber being equipped with a low level sensor and a high level sensor*, as recited in claim 20. In embodiments of the invention, the low and high level sensors are used to determine when the hermetic chamber is full and when it is empty. Data from the low and high level sensors can be used to determine a flow state of the selected channel of the endoscope through which fluid is being directed.

Pfeifer discloses a system in which pump 52 pumps fluid from reservoir 47 to basin 40 via valves 57. Fluid may drain from the basin 40 to the reservoir 47 through valve 44. In contrast to the claimed invention, Pfeifer does not use level sensors at the reservoir 47. Instead, Pfeifer compares data from throughput testing devices 46 and 55 to testing data to determine the flow state of the selected channel of the instrument. Therefore, Pfeifer does not disclose *the hermetic chamber being equipped with a low level sensor and a high level sensor*, as recited in claim 20, and there would be no reason to add such sensors to Pfeifer's reservoir 47.

Graf also fails to disclose *the hermetic chamber being equipped with a low level sensor and a high level sensor*, as recited in claim 20. Graf discloses a tank 10 having a temperature sensor 15 and a pressure sensor 16. However, Graf does not disclose that the tank 10 is a hermetic chamber, much less that the tank 10 has a low level sensor as a high level sensor. Therefore, the applied art fails to disclose or suggest this feature of the claimed invention.

Furthermore, neither Pfeifer nor Graf discloses or suggests *an upper portion of the hermetic chamber being connected to a connection solenoid valve that allows air to evacuate when the hermetic chamber is being filled*, as additionally recited in claim 20. Pfeifer does not disclose a hermetic chamber, much less a valve that allows air to evacuate when the hermetic chamber is being filled. Instead, Pfeifer merely discloses a reservoir 47. Pfeifer is completely silent as to permitting air to evacuate the reservoir 47 during filling of the reservoir 47.

Graf discloses a tank 10. However, Graf does not disclose that the tank 10 is a hermetic chamber, and there is no mention in Graf of a solenoid valve connected to an upper portion of the tank 10, much less a solenoid valve that allows air to evacuate when the tank 10 is being filled. Therefore, Pfeifer and Graf do not disclose or suggest *an upper portion of the hermetic*

chamber being connected to a connection solenoid valve that allows air to evacuate when the hermetic chamber is being filled, as recited in claim 20.

Even further, the applied art does not disclose or suggest *the filling is performed by a circulation pump arranged upstream of the hermetic chamber and which is configured to agitate contents of the tank*, as also recited in claim 20. Pfeifer discloses a circulating pump 52.

However, Pfeifer's pump 52 is arranged downstream of the reservoir 47, and is used to fill the basin 40, which is opposite of the claimed invention. In contrast to Pfeifer, in embodiments of the claimed invention, the circulating pump is arranged upstream of the hermetic chamber and is used to fill the hermetic chamber from the tank. Such is not taught or suggested by Pfeifer.

Graf does not compensate for this deficiency of Pfeifer with respect to the claimed invention. Graf discloses a circulating pump 11; however, this pump 11 is disclosed downstream of tank 10. In any event, tank 10 is not even disclosed as a hermetic chamber. Therefore, no proper combination of Pfeifer and Graf discloses or suggests also fails to disclose *the filling is performed by a circulation pump arranged upstream of the hermetic chamber and which is configured to agitate contents of the tank*, as recited in claim 20.

Still further, neither Pfeifer nor Graf discloses *controlling and recording a time for a fluid flow under pressure within the hermetic chamber to travel from the high level position to a designated low level position when at least one of the valves is open to at least a respective one of the one or more inlet channels*, as recited in claim 20. The Examiner asserts that Pfeifer discloses this feature at lines 1-42 of col. 9, lines 19-62 of col. 3, and lines 1-10 of col. 4. Applicants disagree.

Pfeifer does not disclose recording a time for fluid to travel from a high level position to a low level position in the reservoir 47. Instead, Pfeifer teaches three different methods for

testing the penetrability of the instrument: (i) determining throughput rate at the outlet side (col. 3, lines 60-61), e.g., via throughput testing device 46; (ii) determining throughput rate at the inlet side (col. 3, lines 63-64), e.g., via throughput testing device 55; or (iii) measuring pressure drop over time (col. 3, line 66 through col. 4, line 5). None of these techniques involves measuring the time it takes for a fluid to travel from a high level position to a low level position in the reservoir 47.

For example, techniques (i) and (ii) involve determining instantaneous flow rate at a location between the reservoir 47 and the basin 40, and have nothing to do with measuring a time, much less a time for fluid to travel from a high level position to a low level position in a chamber. While technique (ii) may involve measuring time, it does not involve measuring time for fluid to go from a high level position to a low level position in a chamber. Instead the time measured in technique (iii) is related to a detected pressure drop, and has nothing to do with a time for fluid to travel from a high level position to a low level position in a chamber. Therefore, contrary to the Examiner's assertion, Pfeifer does not disclose *controlling and recording a time for a fluid flow under pressure within the hermetic chamber to travel from the high level position to a designated low level position when at least one of the valves is open to at least a respective one of the one or more inlet channels*, as recited in claim 20.

Graf does not compensate for this deficiency of Pfeifer with respect to the claimed invention because Graf also fails to disclose recording a time for fluid to travel from a high level position to a low level position in a chamber. Moreover, the Examiner does not assert that Graf teaches this feature.

For all of the above-noted reasons, Applicants submit that the applied art does not disclose or suggest all of the features of independent claim 20. Therefore, the applied art does not render the claimed invention obvious.

Claims 21-34 depend from allowable independent claim 20, and are allowable at least for the same reasons as discussed above with respect to claim 20. Moreover, the dependent claims recite features that are not disclosed by the applied art.

For example, no proper combination of Pfeifer and Graf teaches *emptying of the filled hermetic chamber and recording the time for the fluid to reach the low level*, as recited in claim 22. As discussed above with respect to claim 20, neither Pfeifer nor Graf disclose or suggest measuring a time it takes to empty a chamber. Instead, Pfeifer discloses measuring a flowrate using device 46 or 55. However, the flowrate at devices 46 and 55 are independent of the level of fluid in reservoir 47. Moreover, while Pfeifer discloses measuring time associated with a pressure drop, Pfeifer makes no mention of recording the time it takes to empty the reservoir 47. Graf also fails to disclose *emptying of the filled hermetic chamber and recording the time for the fluid to reach the low level*. Nor does the Examiner rely on Graf for teaching this feature.

Accordingly, Applicants respectfully request that the §103 rejection of claims 20-34 be withdrawn.

Request for Rejoinder of Claims Directed to Non-Elected Invention

As independent claims 20-34, directed to the process for measuring and controlling the circulation of fluids in endoscope channels, have been shown to be allowable over the art of record, Applicants request rejoinder of claims 35-39, directed to the apparatus for carrying out the method. More specifically, withdrawn independent claim 35 has been amended to include the special technical feature recited in allowable independent claim 20. Accordingly, Applicants

request that the Examiner consider the merits of claims 35-39 and indicate that these claims, too, are allowable over the art of record.

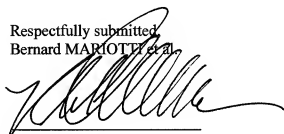
CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

The Examiner is invited to contact the undersigned at the telephone number listed below, if needed. Applicants hereby make a written conditional petition for extension of time, if required. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 19-0089.

Respectfully submitted
Bernard MARIOTTE et al.



Neil F. Greenblum
Reg. No. 28,394

Robert W. Mueller
Reg. No. 35,043

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Greenblum & Bernstein, P.L.C.
1950 Roland Clarke Place
Reston, Virginia 20191
Telephone: 703-716-1191